

No. 3,176,316), Schroeder (US Patent No. 5,671,695), Schmieding (US Patent No. 5,415,651), Seagrave (US Patent No. 5,234,435), and Prewett (US Patent No. 5,507,810).

The Examiner rejected claims 1, 2, 4, and 5 over Bodell. Bodell discloses a plastic prosthetic tendon. Bodell in no way discusses or teaches preserved or packaged grafts for convenient use during surgery, as is provided by the present invention. Applicants suggest that because Bodell teaches a synthetic graft, the need for preservation, as required in claims 1, 2, 4, and 5 would not be obvious. Withdrawal of this rejection is respectfully requested.

Applicants have amended claims 1, 12, and 35 to further distinguish the present invention from the cited art. Claims 1, 12, and 35, as amended, relate to the preservation and sterile packaging of *non-autologous* grafts or replacement ligaments. These amendments highlight the surgical advantage of the invention, namely the ability to have readily available, prepackaged non-autologous grafts as an alternative to harvesting a tendon from within the patient's body, which requires additional surgery time and healing for the patient.

Applicants have also added new claims 37, 38, and 39. Support for claims 37 and 38 is found at least on page 8, line 15. Support for claim 39 is found at least on page 10, lines 14-22.

The Examiner rejected claims 1-3, 5, 7, 10, 11, 35, and 36 as obvious over Schroeder. The Examiner has also rejected claims 1-13 over Schmieding, and claims 1-5, 7, 10, 11, 12, 36, and 36 over Seagrave. In the discussion of each of these rejections, the Examiner concedes that the references do not teach preserving the graft and placing it sterile packaging, yet the Examiner states that states that "it is well known in the art to preserve

implantable prosthetic grafts in sterile packaging for purposes of using in a surgery at a later time.”

Applicants respectfully assert that it is *not* “well known” in the art to preserve the prosthetic grafts of Schroeder, Schmieding, and Seagrave, as each of Schroeder, Schmieding, and Seagrave discloses the use of autografts, which would *not* be preserved in sterile packaging because autografts are harvested and used in the same surgical procedure.

Schmieding discloses that “[t]he bone-patellar tendon-bone graft is harvested together in one piece . . . However, since separate bone blocks must be harvested, several incisions must be made in the patient’s knee to remove the patellar tendon-bone graft.” (Col. 1, lines 62-68.) Schroeder teaches that it is even *standard* for grafting procedures to incorporate the use of autografts: “bone-ligament-bone graft is then harvested, often from the patellar tendon, following *standard* grafting procedures.” (Emphasis added) (Col. 1, lines 22-24.) Finally, Seagrave discloses harvesting of autografts in column 3, lines 59-62. Neither Schmieding, Schroeder, nor Seagrave suggest or disclose preserved or packaged grafts. For at least these reasons, Applicants respectfully request the Examiner’s withdrawal of these rejections.

The Examiner also rejects claims 14 and 15 as obvious over Schmieding in view of Prewitt. Applicants assert that Schmieding is an improper reference for the reasons provided above. Furthermore, in contrast to the Examiner’s contention, Prewitt fails to teach or suggest the assembly and packaging of non-autologous graft tissue, as is required by amended claim 12, from which claims 14 and 15 depend. Prewitt discloses a process for removing cellular debris, antigens, and other irritants from allograft or xenograft tissue so that the tissue will be more acceptable as an implant. The process includes contacting the tissue

with one or more extraction agents for preferably about 8 hours at room temperature with mild agitation. Prewitt does not teach the assembly and packaging of grafts for convenient use during surgery. Therefore, the combination of Schmieding and Prewitt does not teach or suggest the assembled sterile, preserved, and packaged grafts of claims 14 and 15. Accordingly, withdrawal of this rejection is respectfully requested.

Furthermore, none of the cited references teach or disclose preparing non-autologous material by folding and suturing, as disclosed in the present invention. As noted above, Schmieding, Schroeder, and Seagrave all relate to autologous material that is prepared during a surgical procedure. This preparation is done after the autologous material has been harvested, while the patient waits on the operating table. The present invention is advantageous over the cited art in that surgery time is significantly shortened by the provision of a pre-sutured and pre-folded graft.

Because the cited references do not teach or suggest the present invention, it is inappropriate to rely upon them to support an obviousness-type rejection. For all of these reasons, Applicants respectfully request the withdrawal of the Examiner's rejections under §103.

Applicants submit that the above-referenced application is now in condition for further favorable consideration culminating in allowance. Such action is respectfully requested.

It is respectfully requested that, if necessary to effect a timely response, this paper be considered as a Petition for an Extension of Time sufficient to effect a timely response and shortages in other fees be charged, or any overpayment in fees be credited, to the Account of Barnes & Thornburg, Deposit Account No. 10-0435, with reference to Matter No. 26502-64723.

Respectfully submitted,
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